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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT PAPER NUMBER

1624

DATE MAILED: 07/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,320

Applicant(s)

HINZ ET AL.

Examiner

Venkataraman Balasubramanian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicants' response, which included amendment to claims 1-4, filed on 4/21/2003, is made of record.

Claims 1-10 and 12-13 are pending. Applicants should note that claims 1-10 and 12-13 will be examined to the extent they embrace the elected subject matter as noted in the previous office action.

In view of applicants' amendment to claims 1-4, all 112 second paragraph rejection made in the previous office action has been obviated. As applicants' remarks, item 4 under indefiniteness, first of all, examiner cannot see scope difference if the last line is recited as compound..... or pharmaceutically acceptable salt thereof in singular. Secondly, reciting salts would imply more than one salts of the compound at a time is being claimed as compare to a single salt whatever it may be being claimed. Thus reciting the salt of the compound in plural was objected to.

However, applicants' response is incomplete. For example in the amendment of claims 1, it is not clear what structures are included in B. Note claim 1, in B choice recites " the B ring selected from the group consisting of" but no structural choices shown. Similarly, in entry d, it recites a 3-7 membered ring and wherein n is 2 or 3, m is an integer of 1-3 but it is not clear what is being referred to. Hence it is not possible address applicants traversal or understand whether amendment has obviated the rejections made in the previous office action. Hence the following rejections made in the previous office action is maintained

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cerebral diseases, does not reasonably provide enablement for prevention of cerebral diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

This rejection is same as made in the previous office action. In response to this rejection, applicants have suggested that they have evidence for preventing cerebral diseases and would provide a declaration to that effect. However, so far no such declaration was made available to the examiner. Hence this rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Scott et al. WO 97/43240.

Scott et al. teaches several biaryl-oxobutyric acids as metalloprotease inhibitors, which include compounds claimed in the instant claims for the treatment of demyelinating

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disease of the central nervous system. See pages 9-12 for summary of the invention, pages 13-23 for detailed description of the invention, including formula L on page 13, which corresponds to instant generic compound and page 24 for compounds made. See also pages 33-46 for examples of the compound made and the testing of the compounds as metalloprotease inhibitors.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wolanin et al. WO 97/43247.

Wolanin et al. teaches several metalloprotease inhibitors, which include compounds claimed in the instant claims for the treatment of demyelinating disease of the central nervous system and aneurismal disease. See pages 9-12 for summary of the invention, including formula L on page 10, which corresponds to instant generic compound, pages 13-31 for detailed description of the invention, and pages 31-54 for compounds, including Table I on page 38, made. See also pages 55-56 for examples of the testing of the compounds as metalloprotease inhibitors.

Claim 1-10 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Zandt et al. WO 97/43247.

Van Zandt et al. teaches several metalloprotease inhibitors, which include compounds claimed in the instant claims for the treatment of demyelinating disease of the central nervous system, aneurismal disease, thrombosis and tumor metastasis. See pages 10-13 for summary of the invention, including formula L on page 11, which corresponds to instant generic compound, pages 14-23 for detailed description of the invention, particularly note the definition of R^{40} which includes groups claimed for instant

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R⁶. See pages 24-26 for preferred compounds. See pages 45-62 for examples of compounds made especially see Table 1. See also pages 62-68 for examples of the testing of the compounds as metalloprotease inhibitors.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bocan et al. WO 98/26773.

Bocan et al. teaches several metalloprotease inhibitors, which include compounds claimed in the instant claims for the treatment of neurological diseases. See formula shown on page 3 and note the definition of various variable groups. See pages 21-30 for preferred compounds. See entire document for method of use process of making and compounds made and testing of the compounds as metalloprotease inhibitors.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Purchase et al. WO 98/09940.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kluender et al. WO 96/15096.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kluender et al. WO 98/22436.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Dixon et al. WO 97/43245.

Each of the above four references teaches metalloprotease inhibitors bearing the biphenyl-4-oxo or 4-hydroxy-butyric acid for treating diseases which include neurological diseases. Each case see entire document.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Zandt et al. WO 97/43247.

Teachings of Van Zandt et al. as discussed in the above 102 rejection is incorporated herein.

Instant claims require variously substituted biaryl-butyric acids.

Van Zandt et al. teaches the equivalency of exemplified compounds with various substituents with that claimed. See pages 10-23, especially the definitions of various variable groups. Thus it would have been obvious to one having ordinary skill in the art at

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the time of the invention was made to make compounds variously substituted in biphenyl ring and the and the side chain as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Scott et al. WO 97/43240 or Wolanin et al. WO 97/43247 or Bocan et al. WO 98/26773 or Purchase et al. WO 98/09940 or Kluender et al. WO 96/15096 or Kluender et al. WO 98/22436 or y Dixon et al. WO 97/43245.

Teachings of by Scott et al. WO 97/43240, or Wolanin et al. WO 97/43247 or Bocan et al. WO 98/26773 or Purchase et al. WO 98/09940 or Kluender et al. WO 96/15096 or Kluender et al. WO 98/22436 or y Dixon et al. WO 97/43245 as discussed in the above 102 rejection is incorporated herein.

Instant claims require variously substituted biaryl-butyric acids.

Each of the above documents teaches the equivalency exemplified compounds with various substituents with that claimed in the definitions of various variable groups. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted in biphenyl ring and the and the side chain as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

VB

V. Balasubramanian

07/11/2003

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BRUCK KIFLE, PH.D.
PRIMARY EXAMINER